Research Article

Comparison of transcutaneous electrical nerve stimulation (TENS) and functional electrical stimulation (FES) for spasticity in spinal cord injury - A pilot randomized cross-over trial

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Objective: Spasticity following spinal cord injury (SCI) can impair function and affect quality of life. This study compared the effects of transcutaneous electrical nerve stimulation (TENS) and functional electrical stimulation (FES) on lower limb spasticity in patients with SCI.
Design: Double blind randomized crossover design.
Setting: Neuro-rehabilitation unit, Manipal University, India.
Participants: Ten participants (age: 39 ± 13.6 years, C1–T11, 1–26 months post SCI) with lower limb spasticity were enrolled in this study.
Interventions: Participants were administered electrical stimulation with TENS and FES (duration - 30 minutes) in a cross over manner separated by 24 hours.
Outcome Measures: Spasticity was measured using modified Ashworth scale (MAS) [for hip abductors, knee extensors and ankle plantar flexors] and spinal cord assessment tool for spastic reflexes (SCATS). Assessments were performed at baseline, immediately, 1 hour, 4 hours, and 24 hours post intervention.
Results: A between group analysis did not show statistically significant differences between FES and TENS ($P > 0.05$). In the within group analyses, TENS and FES significantly reduced spasticity up to 4 hours in hip adductors and knee extensors ($P < 0.01$). SCATS values showed significant reductions at 1 hour ($P = 0.01$) following TENS and 4 hours following FES ($P = 0.01$).
Conclusion: A single session of electrical stimulation with FES and TENS appears to have similar anti-spasticity effects that last for 4 hours. The findings of this preliminary study suggest that both TENS and FES have the potential to be used as therapeutic adjuncts to relieve spasticity in the clinic. In addition, FES may have better effects on patients presenting with spastic reflexes.

Keywords: Transcutaneous electrical nerve stimulation, Functional electrical stimulation, Spasticity, Spinal cord injury, Spastic reflexes

Introduction

Spasticity is a common complication after spinal cord injury (SCI), and has been reported in approximately 65% of individuals with spinal cord injury.[1] The pathogenesis of spasticity is not completely understood, however increased excitability in the motor neuronal pool is hypothesized as a primary causative mechanism.[2] In addition to spasticity, hypertonia in spinal cord injury also includes multi-joint reflex behaviors, such as flexor and extensor spasms, which are mediated by hyperexcitable interneuronal reflexes.[3–7]

Spasticity can often lead to pain and contractures that are capable of reducing quality of life.[8] However, individuals with SCI can also elicit spasticity and spasms by adopting certain postures to aid functional activities such as transfers.[9] Hence, the appropriate modality for managing spasticity must modulate spasticity to balance its beneficial effects against unwanted side effects. Although pharmacological, surgery, and other therapies can manage spasticity, they may be associated with adverse effects. Non-pharmacological therapies such as serial casting can cause skin breakdown.[10]

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Botulinum toxin is widely used for spasticity reduction, but common side effects include muscle weakness, pain at injection site, and malaise.[11] Moreover, oral anti-spastic agents such as baclofen can cause muscle weakness and may impede functional activities in patients with SCI.[12] Despite their widespread use, there is insufficient evidence to warrant pharmacological agents for reducing spasticity.[13]

Surface electrical stimulation is a therapeutic modality that demonstrates the potential to be less invasive and safer than pharmacological and other therapies to modulate spasticity. Transcutaneous electrical nerve stimulation (TENS) and functional electrical stimulation (FES) are two forms of surface electrical stimulation that are user friendly and can be easily administered by a therapist.

FES activates several muscles electrically in a coordinated and sequenced manner via nerve fibers to produce a particular function. The FES system generates a train of electrical stimuli that trigger action potentials in the intact peripheral nerves which further activate muscle contractions.[14] The magnitude of the stimulus intensity determines the number of nerve fibers activated, and in turn the force of the muscle contraction.[14] Since its inception nearly half a century ago, FES has been applied in varied contexts such as gait training, muscle re-education, and spasticity suppression.[15–17]

Commonly used methods of electrical stimulation to reduce spasticity include stimulation of the spastic muscle which is theoretically mediated via Renshaw cell inhibition[18] and/or recurrent inhibition.[19] Antagonist stimulation is another method[20–22] which may reduce spasticity by increasing reciprocal inhibition via spinal pathways.[18] FES induced cycling appears to reduce spinal spasticity in the short term,[1,23,24] however its beneficial effect and duration of spasticity suppression still remain unclear.[25]

TENS is another non-invasive therapeutic modality commonly used in pain control that exerts its actions by stimulating large diameter mechano-sensitive afferent nerve fibers in the skin.[26] It is hypothesized that TENS may reduce spinal spasticity via mechanisms such as modulating spinal inhibitory circuits,[27] and/or activation of large diameter afferents,[28,29] and/or induction of central nervous system plasticity.[30] While TENS produces spasticity suppression by activating afferents which in turn modulate spinal circuits, FES mediated effects on spasticity are largely due to muscular contraction and its orientation to the spastic muscle (i.e. agonist/ antagonist).[11]

A recent review suggested that TENS is effective for spasticity and the improvements may enhance when combined with physical therapy.[31] Although stimulation parameters, sites of application, and outcomes differ in literature, there is some agreement that TENS can be used as a sensory level electrical stimulation modality for spasticity suppression. Indeed, TENS has been investigated to a greater extent than FES and several studies report a single session of TENS has been effective for reducing spinal spasticity and effects are prolonged with multiple sessions.[32–34]

There is no consensus regarding the appropriate choice of modality for suppressing spasticity in patients with SCI, possibly due to the heterogeneity of this population. Different forms of electrical stimulation are seldom compared which can obscure clinical decisions for managing spasticity. Consequently, it is important that electrical stimulation therapies selectively target spasticity in SCI and address both spasms and hypertonicity for feasibility in clinical practice.

Although, current evidence suggests that TENS and FES can suppress spasticity, yet the duration of their after effects is unclear. Given that both may reduce spasticity, the objective of this study was to compare TENS and FES and measure the duration of after effects on spinal spasticity. Moreover, we incorporated outcomes such as the spinal cord assessment tool for spastic reflexes (SCATS) and modified Ashworth scale (MAS) to evaluate the effect of electrical stimulation on both tonic and reflex spastic behaviors. Therefore, the purpose of this study was to compare, via a pilot randomized crossover trial, the effects of TENS and FES on lower limb spasticity following SCI.

Materials and methods

Study design

This was a prospective double blinded randomized, crossover trial in which clinical assessment was performed at five time points. Each participant received a single session of TENS and of FES on two separate days. The clinical assessments were performed at baseline, immediately, one hour, four hours, and 24 hours post intervention. To minimize diurnal variation in spasticity, the time for administering the intervention was kept constant. An interval of 24 hours was provided between each intervention to minimize carryover effects. This interval compares well with the documented washout period for electrical stimulation.[19] The sequence of intervention was randomly allocated by drawing lots. The study participants and the outcome assessor were blinded to the sequence of intervention. A schematic of the study design is shown in Fig. 1. All participants were informed about the study, and a written informed consent was obtained from everyone. All research methods were approved by the university ethics committee and conformed to the declaration of Helsinki. This trial was prospectively registered in the Clinical Trials Registry India - CTRI/2011/05/001738.

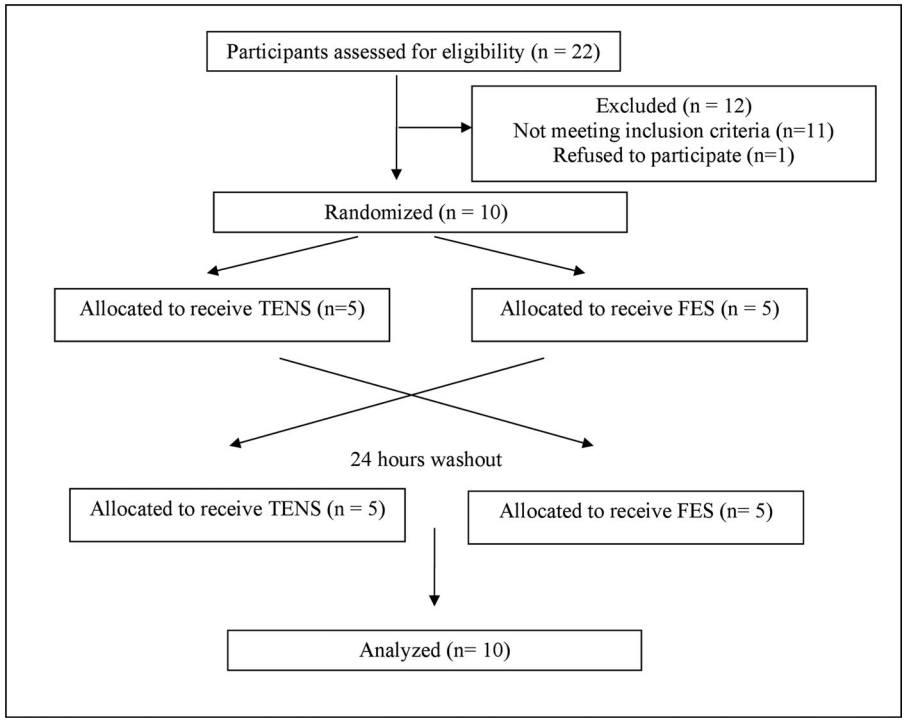

Figure 1 Flow of participants in the trial.

Selection of study participants

Participants were selected for the study based on the following inclusion criteria: (i) diagnosis of traumatic or non-traumatic spinal cord injury above L1 spinal level; (ii) spasticity due to SCI (Grade ≥ 1 as per MAS) in hip adductors, quadriceps or gastro-soleus muscle group/s; (iii) presence of ankle jerk showing recovery from spinal shock. Participants were excluded if they had: (i) presence of metal implants in the affected leg; (ii) unstable medical conditions; (iii) skin infections; (iv) presence of other complications which could increase spasticity like heterotopic ossification; (v) pressure ulcers; (vi) deep vein thrombosis; (vii) edema; (viii) contractures; and (ix) urinary tract infections. All participants were inpatients of a tertiary care hospital and were on a physical therapy rehabilitation program. At baseline, the participant's gender, age, duration post spinal cord injury, and details about anti-spasticity medications were recorded. The neurological level was determined using the American Spinal Injury Association (ASIA) scale. A blinded assessor measured spasticity with the SCATS and MAS (for hip adductors, quadriceps & gastro-soleus muscles).

Interventions

Prior to electrical stimulation, each participant's skin was cleaned with soap and water. The participants were informed about the procedure and were suitably undressed. They were placed in supine for both interventions. For subjects with bilateral lower limb spasticity, stimulation by either TENS or FES was given simultaneously over both lower limbs.

TENS

We used a TENS [ACU-TENS (TechnoMed)] (India) machine with 4 bipolar channels. Biphasic square wave impulses at a frequency of 100 Hz and pulse duration of 300 μs were used for a total duration of 30 minutes. Stimulation was provided by carbon rubber surface electrodes (4 cm × 3 cm) secured to the skin with adhesive tape. For the quadriceps and adductor muscle groups, a single bipolar channel with 2 electrodes was used; one on the anterior (active electrode) and the other on the medial lower thirds of the thigh (return electrode). For the plantar flexors, another bipolar channel was used with two electrodes placed on the calf muscles. Stimulation intensity was increased until further increase caused discomfort. Stimulation intensities did not cause muscle contractions and were not increased beyond 20 mA for individuals who had sensory impairments. This intensity was determined according to previous literature that suggests that 15 mA is twice the perceptual threshold for TENS in healthy individuals.[11]

FES

The Functional Electrical Stimulator (MEGA XP) Cybermedic (Korea) machine used was an 8 channel

stimulator that provided biphasic rectangular pulses at a pulse rate of 35 Hz and pulse width of 300 μs. Other parameters included a ramp up time of 3 seconds, hold duration of 5 seconds, ramp down time of 2 seconds and a rest time of 10 seconds. Total treatment duration lasted 30 minutes. Carbon rubber surface round electrodes (8 cm diameter for quadriceps and adductors, and 6 cm diameter for plantar flexors) were secured to the participant's leg(s) with straps. Larger electrodes were used for the quadriceps and adductor muscles due to the bulk of the muscles. Motor points for each spastic muscle were identified using surface landmarks. The electrode placement was on the medial aspect of the mid-thigh region for hip adductors, on the anterior aspect of the thigh for the quadriceps, and on the calf for the plantar flexors. The stimulation intensity was increased until a visible muscle contraction (motor threshold) was elicited. Thereafter the intensity was increased till 300% of motor threshold[24] as per the participant's tolerance and comfort level.

Measures

Modified Ashworth Scale (MAS)

Outcomes were assessed before and after each intervention by a blinded rater. The MAS was used to quantify the extent of spasticity and each test movement was performed for 1 second before determining spasticity.[35,36] For data analysis, the 1+ value of the MAS was assigned as 2; 2 was assigned as 3 and so on.[24]

Spinal Cord Assessment Tool for Spastic Reflexes (SCATS)

The SCATS is a validated technique for assessing spastic behavior such as clonus, flexor and extensor spasms in spinal cord injury.[37] Clonus, flexor and extensor spasms were scored on a scale from 0 (no reaction) – 3 (severe),[37] and each score was then summed up to a cumulative score from 0 (minimum) – 9 (maximum).

Statistical analysis

Data was analyzed with SPSS for Windows, version 21 (SPSS Inc., Chicago, IL, USA). Due to the small number of participants in this study, data was analyzed using non-parametric tests and results were reported as medians. Spasticity values were compared between the TENS and FES groups with the Wilcoxon signed rank test. All analyses were two tailed and the level of significance was set at 0.05. The Friedman's test was used to detect differences in spasticity across multiple time points within each group. Post hoc tests were performed for each intervention using the Wilcoxon signed rank test. The level of significance was accordingly adjusted to 0.01 using the Bonferroni correction.

Results

Participants

Ten patients with SCI with lower limb spasticity were enrolled in this randomized, double blinded, crossover trial. None of the participants reported any adverse effects with either TENS or FES. At baseline, spasticity was present in both lower limbs of all patients and for data analysis, each leg was considered as an independent sample. However, in the final data analysis we excluded data with spasticity values of zero (post washout) to facilitate an equal comparison between both groups. Ten patients presented with hip adductor spasticity, six with quadriceps spasticity and two with plantar flexor spasticity.

There were nine male participants in this study. The mean age was 39 ± 13.16 years and time since injury was 1–26 months. The demographic characteristics of the study participants are represented (Table 1). The flow of participants through the trial is shown in (Fig. 1). There were no dropouts during this trial. Five participants were on oral baclofen only for managing spasticity and the dosage was constant during the study. On initial admission to the hospital, eight participants underwent surgery and two received conservative management. Seven out of eight participants underwent decompressive laminectomy surgeries and one participant was operated with spinal fusion. There were no differences in spasticity values between the two groups at baseline (Table 2). Table 3 represents the between limb differences in spasticity in both TENS and FES groups.

Trend in spasticity with intervention

Trends for spasticity in hip adductors, knee extensors, plantar flexors and SCATS are represented in Fig. 2. Medians are represented for all variables (except plantar flexors) at different time points for both interventions. Means are represented for plantar flexors as only two participants presented with plantar flexor spasticity. A decline was observed in spasticity values of hip adductors, and knee extensors up to four hours following both interventions (Fig. 2A, 2B). Despite a higher baseline, knee extensor spasticity showed a greater improvement at the 1 hour and four hour evaluations with TENS compared to FES. Although both interventions improved plantar flexor spasticity, FES seemed to show better reductions (Fig. 2C). SCATS values showed better improvement following FES that eventually peaked to baseline values at the 24 hour evaluation (Fig. 2D).

Figure 3 depicts the number of participants who demonstrated an improvement in spasticity (a change of ≥ 1 unit) and those with no change between both

Table 1 Demographic characteristics of study participants.

Patient	Sex/Age	Injury level	ASIA Grade	Etiology	Time since injury (months)	Spasticity management	Initial study group
1	F/30	T10	A	Infective	4	None	TENS
2	M/35	T6	C	Infective	4	None	FES
3	M/30	T11	A	Trauma	1	None	TENS
4	M/60	C6	C	Degenerative	26	Baclofen	FES
5	M/47	C6	C	Degenerative	26	Baclofen	TENS
6	M/50	C4	C	Trauma	1	None	FES
7	M/19	C3	C	Trauma	6.4	Baclofen	FES
8	M/51	C3	C	Tumor	12	Baclofen	TENS
9	M/46	C4	D	Trauma	4.6	Baclofen	TENS
10	M/22	T8	E	Tumor	3	None	FES

ASIA, American Spinal Injury Association. Five participants were receiving baclofen only (and no other antispasmodics) for managing spasticity.

groups. Improvement in plantar flexor spasticity has not been depicted in the figure due to the small sample. Compared to TENS, hip adductor spasticity and SCATS values improved in seven participants at the immediate evaluation post FES. This reduction was maintained up to four hours in about 5–6 participants. Knee extensor spasticity appeared to respond better to TENS as spasticity reductions lasted for 24 hours in four participants. At the 24 hour evaluation for SCATS, 4 participants continued to show improvement with FES but none showed improvement with TENS. Taken together, FES showed a trend towards better improvements in hip adductor spasticity and SCATS values, while TENS appeared to produce better reductions in knee extensor spasticity.

Table 2 Comparison of spasticity values at repeated measurements between the TENS and FES treatment groups.

Group (N)	Baseline	Immediate	1 hour	4 hours	24 hours
MAS - Hip Adductors					
TENS (19)	3	2	2.5	2	3
FES (19)	3	2	2	2	3
P value	0.36	0.12	0.07	0.19	0.53
MAS - Knee Extensors					
TENS (11)	3	2	1	1	3
FES (11)	2	1	1	1	2
P value	0.19	0.54	0.73	0.9	0.6
MAS - Plantar Flexors					
TENS (4)	2.25	1.75	1.75	1.5	1.5
FES (4)	2.25	1.5	1.25	1.25	1.75
P value	1	0.31	0.15	0.31	0.31
SCATS					
TENS (19)	4	3	3	3	3
FES (19)	4	2	2	2	4
P value	0.76	0.06	0.19	0.07	0.32

Values are medians for hip adductor spasticity, knee extensor spasticity, and SCATS. Values are means for plantar flexor spasticity. There were no statistically significant differences at all evaluations between TENS and FES ($P > 0.01$).

Modified Ashworth Scale

All between group comparisons are depicted in Table 2. There were no significant differences for hip adductors, knee extensors and plantar flexors at the immediate, 1 hour, 4 hour and 24 hour evaluations.

A within group analysis revealed a statistically significant difference in hip adductors (χ^2 (4) $=33.7$, $P < 0.001$) and knee extensors ($\chi^2(4) = 22.6$, $P < 0.001$) post TENS application. There were no statistically significant differences in MAS values of plantar flexors ($\chi^2(4) = 6.85$, $P = 0.14$). Post hoc analysis with Wilcoxon signed-rank tests for hip adductors and knee extensors showed statistically significant differences at the immediate, 1 hour and 4 hour evaluations ($P \leq 0.01$), but not at the 24 hour evaluation ($P > 0.01$).

A within group analysis revealed a statistically significant difference in hip adductors ($\chi^2(4) = 41.44$,

Table 3 Spasticity differences between sides (R-L) at repeated measurements for both groups.

Group	Baseline	Immediate	1 hour	4 hours	24 hours
MAS - Hip Adductors					
TENS	0	0	0	0.5	0
FES	-0.5	-1	-0.5	-0.5	-1
MAS - Knee Extensors					
TENS	-0.5	-0.5	-1	-0.5	-1
FES	0.5	0	-0.5	1	-0.5
MAS - Plantar Flexors*					
TENS	0.5	0.5	0.5	0	0
FES	-0.5	0	-0.5	-0.5	-0.5
SCATS					
TENS	-0.5	1	1	0.5	0
FES	-0.5	0	0	1	-1

Values are median differences between right and left sides for hip adductors, knee extensors and SCATS. *Mean differences are represented for plantar flexors. Between side differences are reported only for participants present with bilateral spasticity. Positive values represent greater spasticity in the right side and negative values represent greater spasticity in the left side.

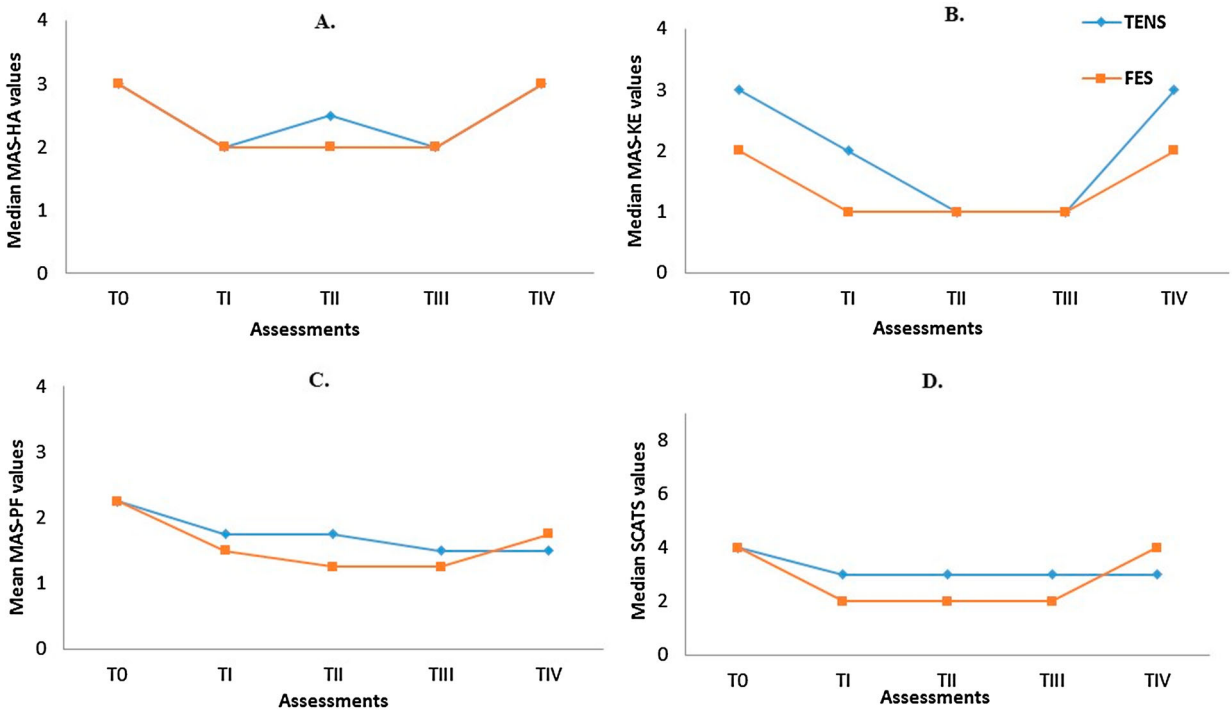

Figure 2 **The top panel (A and B) provides a visual depiction of the trends in hip adductor (MAS-HA) and knee extensor (MAS-KE) spasticity over time with both interventions. The bottom panel (C and D) represents the trends in plantar flexor spasticity (MAS-PF) and SCATS values with both interventions. T0, TI, TII, TIII and TIV were used to denote the evaluation time points – baseline, immediately, one hour, four hours and twenty-four hours respectively. Values are represented as medians for MAS-HA, MAS-KE, SCATS and as means for MAS-PF.**

$P < 0.001$) and knee extensors ($\chi^2(4) = 19.31$, $P = 0.001$) post FES application. There were no statistically significant differences in MAS values of plantar flexors ($\chi^2(4) = 10.18$, $P = 0.3$) post FES. Post hoc analysis with Wilcoxon signed-rank tests for hip adductors and knee extensors showed statistically significant differences at the immediate, 1 hour, and 4 hour evaluations ($P \leq 0.01$), but not at the 24 hour evaluation ($P > 0.01$).

Spinal Cord Assessment Tool for Spastic Reflexes

There were no statistically significant differences in SCATS values across all evaluations between the two interventions (Table 2). There were within group improvements in SCATS values for TENS ($\chi^2(4) = 28.35$, $P < 0.001$) and FES ($\chi^2(4) = 33.66$, $P < 0.001$). Post hoc analysis with Wilcoxon signed-rank tests showed statistically significant differences at the immediate, and 1 hour evaluations ($P \leq 0.01$) post TENS. Evaluation at 4 hours post TENS was not statistically significant ($P > 0.01$). A statistically significant difference was obtained for the immediate, 1 hour, and 4 hour evaluations ($P \leq 0.01$) post FES. Evaluation at 24 hours did not show statistically significant differences post TENS or FES ($P > 0.01$).

Discussion

In this study, we compared and examined the duration of effect of TENS and FES on spasticity in ten participants with SCI. This protocol was safe and well tolerated because our participants did not experience any adverse reactions to either TENS or FES. There were no statistically significant differences between TENS and FES at all evaluations which suggest that TENS and FES may produce similar reductions in spasticity. However, a within group analyses showed that the spasticity suppressing effects of both TENS and FES on hip adductors and knee extensors lasted for 4 hours following both interventions. Moreover, FES reduced SCATS scores significantly up to 4 hours post application. These preliminary findings suggest that TENS and FES reduce lower limb spasticity for 4 hours in individuals with spinal cord injury.

TENS and spasticity

TENS reduced spasticity in hip adductors and knee extensors substantially. Additionally, TENS produced significant improvements in SCATS values. Our findings compare well with previous studies[32–34] on TENS and spinal spasticity. Although these authors predominantly studied plantar flexor spasticity, they found

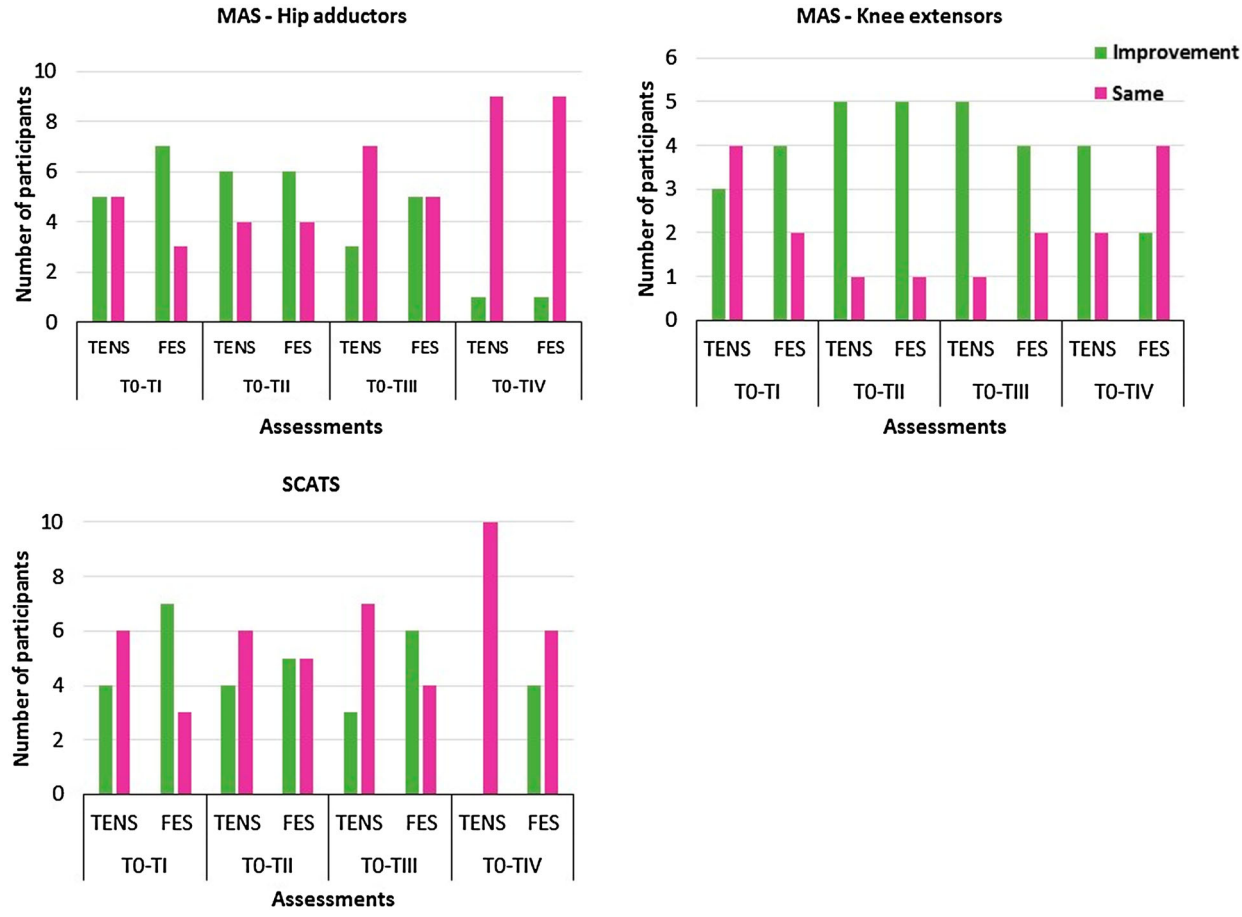

Figure 3 This figure depicts the proportion of participants demonstrating an improvement/or remaining the same in hip adductor (MAS-HA, n = 10), knee extensors (MAS-KE, n = 6) and SCATS variables (n = 10) in both TENS and FES groups. T0-TI, T0-TII, T0-TIII, T-TIV represent the respective changes in baseline-immediate, baseline-1 hour, baseline-4 hours, baseline-24 assessments. None of the participants' spasticity worsened with either TENS or FES. Spasticity was averaged [(R+L)/2] for each participant for each variable. For participants presenting with spasticity in a single limb, only that value was included. A change of ≥1 unit from baseline to each evaluation time point on the MAS and SCATS was considered as an improvement for representative purposes.

significant effects on other measures as well that evaluate spasms in SCI. We observed no differences in plantar flexor spasticity as only two participants presented with minimal spasticity. In a study by Chung *et al.*[34] statistically significant reductions were obtained with 60 minutes of high frequency and low intensity TENS. Aydin *et al.*[32] evaluated the long term effect of TENS and also found significant improvements in spasm frequency scale, deep tendon reflex score and Ashworth values. Current evidence also suggests that long duration TENS with a frequency setting of 100 Hz (used in this study) shows more promise for reducing spasticity than other TENS protocols.[31] Stimulation sites and intensities have varied across literature, and reports suggest that stimulation intensities should be above sensory threshold and just below motor threshold.[38,39] TENS intensities in our study ranged from 20 mA to 30 mA which were tolerable and below the threshold for muscle contraction. TENS is hypothesized to reduce spasticity by stimulating large diameter afferents which can modulate neuronal synaptic reorganization,[27,30] enhance reciprocal inhibition[28] and presynaptic inhibition[30]. This theory is further supported by an animal study[40] which implicates the release of the inhibitory neurotransmitter GABA (Gamma Amino Butyric Acid) in axo-axonal synapses following high frequency TENS. Although our methodology and stimulation parameters differed from others[32,34] in terms of stimulus duration (30 minutes versus 60 minutes), intensity (20–30 mA versus 15 mA) and number of sessions (single session versus repeated application), we believe that TENS reduced spasticity by similar mechanisms as mentioned above.

FES and spasticity

Similar to TENS, FES also reduced spasticity in MAS scores of hip adductors, and knee extensors up to four hours post application. We stimulated the spastic

muscle, based on a previous study[32] which showed better reduction of spasticity compared to antagonist and dermatome stimulation. It is hypothesized that recurrent inhibition of the spastic muscle via the Renshaw cell may account for the reduction in tone.[18] The Renshaw cell has a negative feedback loop to the alpha motor neuron i.e. recurrent inhibition,[18] which is thought to be reduced in patients with spasticity. Electrical stimulation of the agonist muscle is theorized to increase the recurrent inhibition to the alpha motoneuron, and consequently to the agonist muscle thus reducing spasticity.[41,42] Our findings are in consensus with previous studies which have utilized other forms of FES. Granat *et al.*[43] investigated the role of a FES gait program in rehabilitation of patients with incomplete SCI and found a reduction in quadriceps spasticity. Rayegani *et al.*[44] also found a significant reduction in spasticity with electrical passive cycling in veterans with SCI.

Effects of FES on spastic reflexes (SCATS) lasted for four hours unlike TENS. Most of the participants had non-traumatic myelopathies and in addition to tonal changes in spasticity, they presented with spasmodic behavior such as clonus, flexor, and extensor spasms. We observed that SCATS values at baseline were relatively higher (around 5–9) compared to MAS. Flexor spasms in SCI are associated with the flexion withdrawal reflex[7] and extensor spasms can be triggered by a change in hip joint position, particularly extension.[45] The threshold for flexor muscle activation has shown to be reduced in SCI.[7] Electrical stimulation with FES may increase the threshold of spastic reflexes via a muscle contraction which may account for the observed findings. FES may be more effective than TENS for reducing spasmodic behavior and improving functional activities, as both flexor and extensor spasms can interfere with ambulation and transfers.[1,37,45]

The duration of effect of electrical stimulation on spinal spasticity differs across literature. Reports of beneficial effects following electrical stimulation vary between 10 min and 3 hours.[12,46,47] Findings of this study concur with other studies as spasticity suppressing effects of FES and TENS were evident up to four hours post application. The duration of effect is known to be proportional to the stimulation time.[48] The stimulation protocol in this study (30 minutes of TENS & FES) was determined according to previous studies[32,34] that incorporated stimulus durations from 20–60 minutes. These studies showed that effects on spasticity may range from short term (minutes) to longer term (hours).

We incorporated a 24 hour interval between the two interventions as previous studies on short term electrical stimulation[19,49] suggest that effects of electrical stimulation on spasticity do not last more than 24 hours. However, it was noted that the spasticity remained below baseline values even after 24 hours following TENS precluding the inclusion of this data in our analysis. We did not expect reductions in spasticity to outlast 24 hours. It is unclear if our washout period was inadequate or other confounders such as diurnal variation in spasticity and/or baclofen influenced the results.

The heterogeneity of our participants could contribute to the observed findings of this study. Previous literature on electrical stimulation and spinal spasticity has targeted spasticity in traumatic, complete SCI patients. However, most participants in this study had different etiologies for SCI (degenerative, neoplastic and infective), variable time since injury (1–26 months) and incomplete lesions. Although it is unclear at this point, these factors could have potentially influenced the magnitude of baseline spasticity (higher MAS and SCATS values) and the subsequent response to electrical stimulation.

Study limitations

Our study has several methodological, technical, and interpretive limitations. We examined the effects of a single session of TENS and FES in this study. More sessions may be warranted to evaluate and compare long term effects. We did not perform concealed allocation in this study. The chosen outcomes for this study were pertinent to SCI, but they were subjective and did not incorporate patient perception of spasticity. Despite widespread clinical use, the MAS is not a reliable outcome measure as it shows poor inter-rater reliability or inter session reliability.[50] Further, we did not incorporate a sham group for comparing interventions. We used a single bipolar channel (TENS) for stimulating both the adductors and quadriceps due to their proximity, but it may have been inadequate for obtaining optimum stimulation. Larger, multi session trials incorporating sham stimulation sessions and more objective spasticity measures such as biomechanical tools are recommended to compare these interventions and study their effects in detail. Future research is also warranted to determine the optimal dosage of electrical stimulation such as frequency, duration, intensity, pulse width, and other parameters for managing spasticity related outcomes. Nevertheless, this study illustrates that FES and TENS are equally promising, and both can be used as an adjunct to exercise or therapy during SCI rehabilitation.

Conclusions

Preliminary findings from this study suggest that both TENS and FES may show potential for improvement in patients with tonal spasticity (i.e. increased MAS values) and FES may produce greater effects in patients presenting with spasmodic behavior and spastic reflexes. Although our findings suggest that a single session of TENS or FES may reduce spasticity for 4 hours, further research is needed to validate these findings. Our study provides a guideline for implementing TENS and FES in larger sham controlled clinical trials.

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Disclaimer statements

Contributors Anjali Sivaramakrishnan, John M Solomon, and Natarajan Manikandan participated in study conception, data acquisition, analysis, manuscript drafting and revisions.

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